

EXHIBIT #2

**UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA**

**CASE No.: 06-21116-CIV-UNGARO-BENAGES
MAGISTRATE JUDGE JOHN J. O'SULLIVAN**

LANA C. KEETON,

Plaintiff Pro Se,

vs.

ETHICON, INC., (d/b/a GYNECARE WORLDWIDE) a New Jersey corporation;
JOHNSON & JOHNSON, a New Jersey corporation,

Defendants.

_____/

PLAINTIFF PRO SE LANA C. KEETON'S

**MOTION FOR CONTEMPT OF COURT AGAINST DEFENDANTS AND
FOR SANCTIONS FOR SPOILIATION OF EVIDENCE**

Plaintiff Pro Se Lana Keeton is, and has been, searching for discoverable truth to prove her allegations against Ethicon, Inc., Gynecare Worldwide and Johnson & Johnson, the Defendants. Throughout the discovery process, Defendants have withheld the quality control reports for the sterilization of the Gynecare TVT System and its TVT device.

Plaintiff contracted a disfiguring, life threatening infection, necrotizing fasciitis, as a result of the implantation of the Gynecare TVT System and its TVT Device in December 2001. The infection started at the left exit incision of the Gynecare TVT Device. (EXHIBIT #1) Medical report from Cleveland Clinic Florida

Necrotizing fasciitis is an extremely rare infection, affecting only about 1,000 victims per year in the entire United States, a country of 300 million people. Of the 869

reported complications from the implantation of the Gynecare TVT Device using the Gynecare TVT System, two women in addition to Plaintiff contracted necrotizing fasciitis during the implantation of the TVT Device. Three, of Eight Hundred Seventy reported complications, is an alarming and staggering number considering the rare occurrence of this devastating killer infection. (COMPOSITE EXHIBIT #2)

Defendants, Ethicon Inc (d/b/a Gynecare Worldwide) and Johnson & Johnson have a history of putting un-sterilized medical devices into the marketplace. The U.S. Food and Drug Administration (FDA) closed a malfunctioning sterilization facility in San Angelo, Texas in the early 1990's after a surprise visit to the facility. Three million four hundred thousand (3,400,000) unsterilized Vicryl sutures were put into the stream of commerce. Again, in April of 2001 Ethicon recalled 1,248,876 vicryl sutures sterilized at its' San Angelo, Texas plant as possibly non-sterile sutures. (EXHIBIT #3)

PLAINTIFF'S DISCOVERY CONTINUALLY THWARTED BY DEFENDANTS

Plaintiff has been requesting Quality Control Reports for the Sterilization of the Gynecare TVT Device since October 11, 2006. Defendants have not produced these documents, despite a Court Order from Magistrate Judge John J. O'Sullivan

1. Plaintiff's Request for Production, October 11, 2006:

“(6) Provide a true copy of all quality control reports for sterilization of the Gynecare TVT Device and prolene mesh tape from 1996 to the present.” (EXHIBIT #4)

2. Court Order by Judge John J. O'Sullivan April 11, 2007 to produce the quality control reports for sterilization for the years 2000 and 2001. Docket #82 (EXHIBIT #5)

Defendants have not complied with this Court Order. Defendants are in contempt of court.

3. Defendants filed a Notice of Service of Compliance with Court Order on April 24, 2007. Docket # 89 (EXHIBIT #6)

4. Defendants Ethicon, Inc.'s and Johnson & Johnson's Compliance with Court Order actually received by Plaintiff states the following:

"5. With respect to Request No. 6, quality control reports are being copied in *Switzerland* and will be provided upon receipt." (EXHIBIT #7)

5. On May 7, 2007 Defendants produced 4,470 pages (LK000291 through LK004760).

Documents are quality control reports for manufacturing. Manufacturing is done in Switzerland at Ethicon Sarl. The documents are written in French. The documents produced are not quality control reports for sterilization. (EXHIBIT #8)

6. Sterilization of the Gynecare TVT System and its TVT Device is accomplished at Ethicon Ltd in Scotland. (EXHIBIT #9)

LK: SUPP00007 top of page reads:

"Johnson & Johnson, Neuchatel, Process specification, Spec#EPC002, Revision: C, page 2/1010:

"1.0 Description

This specification describes the materials, methods, and procedures required to sterilize by ethylene oxide at Ethicon Ltd, Scotland, TVT products manufactured at Ethicon Sarl, Neuchatel [Switzerland]."

LK: SUPP000009 middle of page reads:

"9.0 MATERIALS HANDLING DURING VARIOUS STAGES OF THE PROCESS

Each pallet will be marked regarding its status as it moves through various stages of the process. Ethicon Sarl shall identify material as "Non-sterile Work in Process" (see Annex 1) Ethicon Ltd shall identify material after processing as "Sterilized Awaiting Test Results" (see Annex 2) or equivalent wording."

7. The sterilized product is then returned to Johnson & Johnson Neuchatel, Rue Giradet 29, 2400 Le Loche, Switzerland. LKSUPP00009/LKSUPP000010 (EXHIBIT #9)

Defendants falsely claim that Johnson & Johnson is not involved in this process. Defendant Johnson & Johnson produced no documents in reply to Plaintiff's Request for Production of Documents. (EXHIBIT #10)

8. Defendants May 2, 2007 e-mail, further evidence of non-compliance with Court Order:
"The remaining documents (quality control reports, etc>) from Switzerland totaling Approximately 2500 pages should be available by the end of the week/Monday of next week. We will send them to you upon our receipt." (EXHIBIT #11)

9. Plaintiff notified Defendants May 23, 2007 that these documents were unresponsive to the Court Order. Defendants' response on May 25, 2007 was that all documents had been produced. Defendants should be sanctioned for spoliation of evidence.(EXHIBIT #12)

10. The quality control reports requested do exist and are kept in the ordinary course of business.The Gynecare TVT System has a five (5) year shelf life. (EXHIBIT #13)

11. Plaintiff has never requested quality control reports for manufacturing, in an Interrogatory nor in a Request for Production of Documents as suggested by Defense Counsel Neville Leslie at a hearing before Judge O'Sullivan on July 9, 2007.

Plaintiff is not responsible to Defendants for an invoice for copying charges for \$1,117.50 for 4,470 pages of unrequested, unresponsivedocuments. (EXHIBIT #14)

CONCLUSION

Defendants have exhibited egregious behavior throughout the discovery process.

Plaintiff Pro Se has had to file repeated Motions to Compel to obtain much needed Discovery from the Defendants. The Court is well aware of these Motions, as more than one discovery hearing has been conducted by Judge John J. O'Sullivan. Judge O'Sullivan has ruled more than once that the discovery should be forthcoming, through inspection of the documents at the offices of the Defendants in Somerville, New Jersey and in Orders

to produce the requested discovery documents. Defendants and their Defense Counsel have to be held accountable for their non-compliance of the Federal Rules of Civil Procedure governing discovery.

Plaintiff asks the Court to find the Defendants in Contempt of Court for not complying with Judge O'Sullivan's Order of April 11, 2007.

Plaintiff asks the Court to direct the Jury that the Defendants have withheld salient, extremely valuable discovery and that Plaintiff's case is severely harmed by this withholding of the quality control reports for sterilization.

Plaintiff ask the Court to direct the jury that the trier of fact may presume the contents of the destroyed discovery documents would have been adverse.

Plaintiff asks the Court to sanction the Defendants for spoliation of evidence.

Defendants were put on notice of potential litigation when the first woman died from surgical implantation of the Gynecare TVT Device using the Gynecare TVT System in 1999. (EXHIBIT #15)

Defendants were put on notice of potential litigation when the second woman died from surgical implantation of the Gynecare TVT Device using the Gynecare TVT System in 2000 (EXHIBIT #16)

Discovery documents requested should have been maintained once Defendants were on notice of litigation. Death from the use of the Defendants product, the Gynecare TVT System and its' TVT Device, was certainly adequate notice.

Plaintiff asks the Court to sanction the Defense Counsel for spoliation of evidence. Defense Counsel has not properly advised the Defendants of their responsibilities in record retention policies and procedures. Lead Defense Counsel, Jeffrey B. Shapiro, participates and contributes to legal forums on spoliation and is fully and completely aware of his responsibilities to his client. Defense Counsel should be held accountable for the non-production of discovery documents by the Defendants.(EXHIBIT #17, page 7, second paragraph, quote from Mr. Shapiro, a total of 11 quotes from Mr. Shapiro are in the 15 page document)

It is not unusual for Courts to grant monetary sanctions against large companies who endanger the public by their negligent behavior. Plaintiff asks the Court to consider monetary sanctions for the flagrant abuse by the Defendants of the discovery process.


Plaintiff asks the Court for any other relief deemed proper and fit due to the Contempt of Court, Spoliation of Evidence, and overall negligent behavior of the Defendants.

Plaintiff asks the Court for any other relief deemed proper and fit due to the Contempt of Court, Spoliation of Evidence, and overall negligent behavior of the Defense Counsel.

Dated: August 3, 2007

Miami Beach, FL 33140

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by U.S. mail this
3 day of August, 2007 on all counsel or parties of record on the attached service list.



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